Paper No. 11

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte MARK S. ANDREW and MYLINA ANDREW

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Appeal No. 2001-0550
Application No. 09/030,792

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ON BRIEF

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Before FRANKFORT, STAAB, and MCQUADE, *Administrative Patent Judges*.

STAAB, *Administrative Patent Judge*.

DECISION ON APPEAL

Mark S. Andrew et al. appeal from the examiner's final rejection of claims 1-15, all the claims pending in the application.

Appellants' invention pertains to a method (claims 1-12 and 15) and apparatus (claims 13 and 14) for liquefying target tissue within a body and aspirating the same while leaving non-target tissue intact. A further understanding of the invention can be derived from a reading of claims 1 and 13, reproduced below:

1. A method for liquefying solid tissue within a body comprising the steps of:

heating a biocompatible fluid;

presenting said fluid to target tissue within a surgical area so that said target tissue is liquefied when contacted with said heated fluid while leaving non-target tissue intact; and

aspirating said melted target tissue.

13. A liquefaction apparatus for liquefying solid tissue within a body comprising:

a source of heated solution;

means for directing said heated solution to the tissue in order to liquefy only the tissue;

means for irrigating the tissue while the heated solution is being applied to the tissue; and

means for aspirating the liquefied portion of the tissue.

The references applied in the final rejection are:

Spina et al. (Spina)	4,191,176	Mar. 4, 1980
Matsunaga et al. (Matsunaga)	4,436,722	Mar. 13, 1984
Dieras et al. (Dieras)	4,804,364	Feb. 14, 1989
Masterson et al. (Masterson)	5,653,692	Aug. 5, 1997

Claims 13 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dieras.

Claims 1, 8 and 15 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Masterson.

Claims 1, 2, 9 and 11 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as being obvious over Spina.

Claim 10 stands rejected under 35 U.S.C. § 103 as being unpatentable over Spina in view of Matsunaga.

Claims 12 and 15 stand rejected under 35 U.S.C. § 103 as being unpatentable over Spina in view of Dieras.

Claims 3-7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Masterson "in view of applicant's [sic, applicants'] disclosure" (answer, page 8).[1]

Claims 1, 2 and 9-14 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of US Patent 5,616,120.

Claims 1, 2, and 9-14 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent 6,074,358.[2]

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[1]Based on the totality of the record before us, it is clear that the examiner intends this rejection to be based on the admitted prior art as set forth in the "Background" section of appellants' specification, and in particular on the prior art as exemplified by the patents discussed on page 2 of the specification.

[2]In the final rejection, this ground of rejection was characterized as being "provisional" because it was based on then pending application 08/823,713. Subsequently, said application

Reference is made to appellants' brief (Paper No. 9) and to the examiner's answer (Paper No. 10) for the respective positions of appellants and the examiner regarding the merits of these rejections.

Discussion

The double patenting rejections

Considering first the double patenting rejection based on U.S. Patent 5,616,120, appellants expressly state on page 13 of the brief that "[w]hile Appellants do not fully agree that such a rejection is appropriate, they will submit an appropriate Terminal Disclaimer to obviate the same upon an indication of allowance of claims commensurate in scope with Claims 1, 2, and 9-14."

As to the double patenting rejection based on U.S. Patent 6,074,358, appellants expressly state on page 13 of the brief that "[they] will submit an appropriate Terminal Disclaimer to obviate the same when Claims 24-40 of Appellant's [sic,

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issued as U.S. Patent 6,074,358, thus removing the "provisional" status of the rejection. In addition, because the "provisional" rejection in the final rejection was founded on all the claims of the '713 application (i.e., claims 24-40), we likewise now consider the standing rejection based on the '358 patent to be founded on all the claims thereof (i.e., patent claims 1-9).

Appellants'] co-pending application[s] are allowed and upon allowance of claims commensurate in scope with Claims 1, 2, and 9-14."

In that appellants have chosen not to present any substantive argument directed to the merits of these rejections, but have simply offered to submit terminal disclaimers to obviate them upon allowance of claims commensurate in scope with the appealed claims, these rejections of claims 1, 2 and 9-14 are summarily affirmed.

The anticipation rejection of claims 13 and 14 based on Dieras

Independent claim 13 is directed to a liquefication apparatus comprising "a source of heated solution," a means for directing the heated solution to tissue to be treated, means for irrigating the tissue, and means for aspirating the liquefied portion of the tissue.

Dieras pertains to an ultrasound apparatus for the curettage or exeresis of biological tissue by irrigation of a liquid subject to cavitation and by suction of the disaggregated tissue (abstract). The examiner directs our attention to the Figure 8 embodiment and finds correspondence between lumens 37 and 14 and the annular space between tubes 14 and 16 of the Figure 8 embodiment and the various "means" of claim 13. Concerning the

claim requirement for "a source of heated solution," the examiner proffers the following theory as to why claim 13 does not distinguish over Dieras:

> The examiner maintains that a "heated solution" is a relative term that requires a datum point. For instance, a "heated solution" that has a temperature above body temperature has a defined range. However, the term "heated solution" by itself, does not specify or limit the claims to any particular range of values. A solution that is room temperature can be considered a heated solution relative to that having a temperature near freezing. Thus the term heated solution cannot be held to define over the Dieras et al[.] reference and thus Dieras et al[.] is considered to anticipate claim 13. [Answer, paragraph spanning pages 3 and 4.]

We presume that the element or elements of Dieras the examiner is attempting to read the claim term "source of heated solution" on is one or the other of the (unillustrated) sources of fluid that presumably exist for supplying fluid to the lumens 37 and 14. Unlike the examiner, we do not see that either one of these elements can be construed as "a source of heated solution" when such language is given its broadest reasonable interpretation consistent with appellants' specification as such would be understood by one of ordinary skill in the art (*In re Sneed*, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983); *In re Tanaka*, 551 F.2d 855, 860, 193 USPQ 138, 141 (CCPA 1977)).

Appellants' disclosure (see, for example, page 4, lines 13-16, of the specification) makes reasonably clear that the "source of heated solution" in question is not simply a container or receptacle that is capable of supplying a solution at an elevated temperature, but rather includes something (such as a heating element) to elevate the temperature of the solution. The examiner's view to the contrary is arbitrary and unreasonable in that, in effect, it renders the term "heated" in the claim meaningless.

In that the examiner does not contend that the Dieras device includes anything for elevating the temperature of the fluids delivered by the lumens thereof above ambient, and in that it is not apparent to us that any such means exist in the device of Dieras, the examiner's anticipation rejection of claim 13, as well as claim 14 that depends therefrom, cannot be sustained.

The anticipation rejection of claims 1, 8 and 15 based on Masterson

Masterson relates to "the field of thermal ablation where heat is delivered to necrose or ablate a diseased body organ. More specifically, the invention provides methods and devices for thermally ablating hollow body organs, such as the uterus, by

heating a thermally conductive fluid disposed within the organ" (column 1, lines 8-14). In Masterson, a thermally conductive fluid and a heating apparatus are introduced into the hollow body organ, and the heating apparatus is then activated to heat the fluid within the hollow body organ. A further explanation of the heating apparatus and how it works is found at column 7, lines 31-52. The fluid is heated to a temperature in the range from about 60°C to 100°C (140°F to 212°F) to necrose or destroy the lining of the organ (column 6, lines 3-6; column 6, line 66 to column 7, line 1). Masterson's device includes an impeller 50 within the hollow body organ for circulating the fluid to provide a more uniform temperature distribution. The impeller additionally functions to cut up clots or tissue particles which may be in the fluid and which can affect the temperature distribution (column 7, lines 62-67; column 10, lines 3-6).

Method claim 1 includes the step of presenting heated fluid to target tissue "so that said target tissue is liquefied," and the step of "aspirating said melted target tissue." Concerning liquefying target tissue, the examiner contends that

> the provision that the target tissue be liquefied in the claim would seem to be carried out during the disclosed Masterson et al[.] process. Since the

> Masterson et al[.] method essentially irrigates the uterus and at a temperature within applicant's [sic, applicants'] disclosed range, one would expect the same results to occur for Masterson et al[.] as well as applicant[s]. [Answer, page 5.]

As to the aspirating step, the examiner maintains that in Masterson "a final withdraw step of the fluid is performed by a vacuum (i.e.[,] aspiration) created by a tube connected to the instrument lowered below the level of the uterus (column 11[,] lines 20-25)" (answer, page 5).

While we appreciate the examiner's positions in these matters, we find ourselves in agreement with appellants that Masterson does not anticipate method claim 1. Regarding the step of presenting heated fluid to the target tissue to liquefy said target tissue, we appreciate that Masterson's temperature range for heating liquid of from about 60°C to 100°C (140°F to 212°F) is encompassed by appellants' disclosed temperature range of between 98.6°F and 250°F (specification, page 4). However, we find no express disclosure that Masterson's target tissue (i.e. the lining of the hollow organ) is liquefied, and the examiner has presented no convincing argument that the target tissue of Masterson is necessarily liquefied. In this regard, mere possibilities or even probabilities are not enough. *See In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Moreover, we do not agree with the examiner that Masterson's method necessarily includes the step of "aspirating" target tissue from the hollow organ. A careful reading of the entire paragraph that includes the portion of Masterson's disclosure referred to by the examiner (i.e., column 11, lines 20-25) makes clear that vacuum generating step described therein relates to the *initial* filling of the uterine cavity with fluid *prior to* any heating step.

In light of the above, the anticipation rejection of claim 1, as well as claims 8 and 15 that depend therefrom, based on Masterson cannot be sustained.

The anticipation/obviousness rejection of claims 1, 2, 9 and 11 based on Spina

Spina pertains to a procedure for intralenticular cataract therapy which involves introducing a concentrated solution of a trypsin enzyme into the cataractous lens, allowing sufficient time (e.g., 12-96 hours) for the enzymatic digestion of the lens, and then removing the softened or liquefied lens by conventional aspiration and irrigation techniques. Column 1, lines 40-49; column 3, lines 16-31.

The dispositive issue with respect to the examiner's rejection of claim 1 based on Spina is whether Spina discloses or suggests the step of heating the enzyme solution prior to its introduction into the lens. The examiner's position with respect to this claim limitation is set forth on page 6 of the answer and reads as follows:

> While Spina et al[.] does not teach that the solution is heated, the examiner, having worked in several laboratories personally, considers it inherent or obvious that the solution is heated prior to placing it in the eye for several reasons. Note that in handling the enzymes (column 7[,] lines 30-31) the enzyme aliquot is *thawed* prior to use. Trypsin as well as the reaction mixtures are typically stored in refrigerators or on ice since these specialized proteins are easy degraded near room temperature either by autodegradation or by other proteases which degrade the enzyme causing it to loose it's catalytic activity. Additionally, it is unlikely that the physician would directly inject a patient[']s eye with a solution that is ice cold for obvious reasons of patient comfort. But more importantly, enzymes such as trypsin function most optimally at temperatures above room temperature. This is common knowledge to those familiar with enzymes. Also, see the notes at the bottom of column 5 of Spina in which an in vitro experiment was performed at 37°C (i.e[,] body temperature 98.6°). Thus the examiner considers it inherent and/or obvious to provided [sic] a chilled enzyme solution that is heated before introduction into the eye. Both the heat and the enzyme will both help to liquefy the cataract lens and hence, each and every limitation of the claim is taught.

Concerning anticipation, the examiner has not directed us to any disclosure in Spina that expressly states that the enzyme solution is heated, nor has the examiner apprised us of any evidence or scientific reasoning that would form a basis for concluding that Spina's enzyme solution *necessarily* is heated. In this matter, we again note that possibilities or probabilities are not enough. *In re Oelrich*, 666 F.2d at 581, 212 USPQ at 326. Accordingly, Spina does not anticipate the step of claim 1 of heating the biocompatible fluid.

As to obviousness, rejections based on 35 U.S.C. § 103 must rest on a factual basis. *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968), *reh'g denied*, 390 U.S. 1000 (1968). In making such a rejection, the examiner has the initial duty of supplying the requisite factual basis and may not, because of doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *Id.* Here, the examiner has not advanced any factual basis to support the conclusion that it would have been obvious to one of ordinary skill in the art to heat the enzyme solution of Spina prior to its introduction in the eye. More particularly, even if we accept the examiner's assertion that it

is common knowledge in the art that trypsin functions most optimally at temperatures above room temperature, it is not clear to us that preheating the enzyme solution would be of any practical benefit in the practice *of Spina's method*. As we see it, given the relatively long time period (12-96 hours) over which Spina's enzyme works, and the elevated temperature that exists within the eye relative to room temperature, it may very well be that any initial preheating of the enzyme would have, at best, only a negligible effect on the overall efficiency of Spina's method. The mere fact that the prior art *could* be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification (*see In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). Spina contains no such suggestion.

For these reasons, the rejection of claim 1, as well as claims 2, 9 and 11 that depend therefrom, as being anticipated by or, in the alternative, obvious in view of Spina will not be sustained.

The obviousness rejections of claim 10 based on Spina in view of Matsunaga, claims 12 and 15 based on Spina in view of Dieras, and claims 3-7 based on Masterson "in view of applicant[s'] disclosure"

With respect to claim 10, we have carefully considered the teachings of Matsunaga as it relates to Spina. For the reasons set forth above in our discussion of the rejection of claim 1 based on Spina, we do not consider that Matsunaga would have motivated one of ordinary skill in the art to preheat the enzyme solution of Spina. Therefore, the rejection of claim 10 further in view of Matsunaga will not be sustained.

Concerning claims 12 and 15, we have also considered the teachings of Dieras as they relate to Spina, but conclude that they are not sufficient to make up for the deficiencies of Spina previously noted. Accordingly, the rejection of claims 12 and 15 also is not sustainable.

Finally, the additional teachings of the prior art patents mentioned on page 2 of appellants' specification do not make up for the deficiencies of Masterson. The rejection of claims 3-7 therefore will not be sustained.

Conclusion

The obviousness-type double patenting rejection of claims 1, 2 and 9-14 based on claims 1-6 of US Patent 5,616,120, and the obviousness-type double patenting rejection of claims 1, 2, and 9-14 based on claims 1-9 of US Patent 6,074,358, are affirmed.

All other rejections are reversed.

The decision of the examiner finally rejecting the appealed claims is affirmed-in-part.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

CHARLES E. FRANKFORT Administrative Patent Judge	)	
LAWRENCE J. STAAB Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
JOHN P. MCQUADE Administrative Patent Judge	)	

LJS:hh

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